

REMARKS

The Office Action mailed April 30, 2010, was reviewed and the comments of the Patent and Trademark Office were considered.

Claims 1 – 6, 9 – 10, 13 – 22 and 24 were pending in the application. Claims 7, 8, 11, 12, 16 and 23 has been canceled without prejudice. Claims 1, 4 – 6, 9 – 10, 13, 17 – 19 and 22 have been amended by this response. Amendments other than those to dependent claims 9 and 10 are made for clarification purposes and are not related to the outstanding Office Action. Support for the amendments may be found at, for example, the original specification paragraphs 0095, 108, 109, abstract and claims. In particular, additional compounds listed in Claim 1 or 9 as hydrophobic compound B are described in Specification paragraphs 0108 - 0109 of the published application. The following European numbers for food additives have been replaced by their corresponding name (for reference, See Exhibit A, which is a printout of the website http://en.wikipedia.org/wiki/E_number): E901 is wax white, E907 is wax microcrystalline and E903 is Carnauba wax.

Applicants respectfully submit that no new matter has been added by the amendments. Therefore, claims 1 – 6, 9 – 10, 13 – 15, 17 – 22 and 24 are pending in the application and submitted for reconsideration.

Withdrawal of the rejections and allowance of all pending claims are respectfully requested.

Interview Summary

Applicants appreciate the interview courteously granted to Applicants' representatives July 28, 2010. During the interview the rejection based on the Garthwaite reference was discussed as well as the proposed clarifying amendments to the claims. The contents of the interview are incorporated into the amendments and remarks herein.

Rejections under 35 U.S.C. § 112

Claims 9 - 10 are rejected under 35 U.S.C. 112, second paragraph.

Claims 9 - 10 are patentable under 35 U.S.C. 112, second paragraph because they are particularly pointing out and distinctly claiming the subject matter which applicants regard as their invention. The Examiner has rejected the claims as depending on a cancelled claim. Applicants have corrected the dependencies of Claims 9 and 10. Withdrawal of the rejection and allowance of all claims are respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1 - 6, 9, 10, 13 - 22 and 24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Garthwaite et al. (U.S. Pre-Grant Publication No. 2002/0132001), hereinafter "Garthwaite".

Claims 1 - 6, 9, 10, 13 - 15, 17 - 22 and 24 are patentable over Garthwaite. Claim 16 has been canceled. Withdrawal of the rejection and allowance of all claims are respectfully requested.

The Examiner suggests that the claimed coating compositions are anticipated by Garthwaite. At Office Action page 4, ll. 14-16, the Examiner alleges that Garthwaite teaches "In addition to the polymers, the coating layer typically includes a lubricant such as hydrogenated vegetable oils [0155], [0124] and [0125] (e.g. Sterotex, which is hydrogenated cottonseed oil)."

Applicants respectfully disagree. In paragraph 0155 of Garthwaite, hydrogenated vegetable oils are not mentioned.

Furthermore, paragraphs 0124 and 0125 of Garthwaite do mention hydrogenated vegetable oils, but Garthwaite is listing lubricants for **the core**, not constituents of the **coating**. As explained in paragraph 0126 of Garthwaite, "such lubricants, if present, constitute in total about 0.1 % to about 10 % [...] by weight of the core." Therefore, these particular lubricants of Garthwaite are intended for the core, not a coating.

At Office Action page 4, ll. 16-18 the Examiner alleges that Garthwaite teaches: "The polymeric coating is taught as comprising about 10 - 50 % by weight of polymerized acrylates [0148] and the lubricants, if present, are taught as ranging between 0.1 - 10 % by weight [0126]."

Here again, Applicants respectfully disagree. In paragraph 0126 Garthwaite teaches concentration of lubricants in the core; these are not constituents of the coating.

The only paragraphs where lubricants in any coating are even mentioned are paragraphs 0155 - 0157 of Garthwaite. No ratio is taught except for surfactants in "an amount of zero to 2 % of the film-forming polymer weight." Garthwaite at paragraph 0156. As a consequence, there is no teaching in Garthwaite of a dosage form having a coating composed of a hydrophilic polymer A and a hydrophobic compound B wherein the weight ratio B/A is between 0.5 and 1.5.

Furthermore, the microparticulate oral pharmaceutical dosage form of claim 1 releases the active principle **in the stomach** after a predetermined residence time. In contrast, Garthwaite discloses only enteric coatings, which, by definition, do not release in the stomach and release **in the intestine**. See Garthwaite at paragraph 0102.

Therefore, Garthwaite does not teach a coating for release in the stomach as claimed. For example, paragraph 0102 of Garthwaite discloses an enteric coating that must survive passage of the dosage unit through the stomach into the intestinal tract. Paragraph 0145 of Garthwaite discloses that the hydratable enteric coating diffusion barrier preferably comprises one or more film-forming polymers that are acid- and water-insoluble under stomach conditions. In contrast, the claimed invention is to a coating that releases the active principle in the stomach, after a predetermined residence time.

Garthwaite does not teach a composite coating comprising hydrophilic polymer A and a hydrophobic compound B with a B/A ratio between 0.5 and 1.5, and does not teach the release in the stomach of the active principle after a lag time.

Therefore, independent claim 1 is patentable over Garthwaite. Dependent claims 2 - 6, 9, 10, 13 - 15, 17 - 22 and 24 depend from independent claim 1 and add further patentable features to the patentable features of independent claim 1. Thus, claims 1 - 6, 9, 10, 13 - 15, 17 - 22 and 24 are patentable over the cited reference. Withdrawal of the rejection and allowance of all claims are respectfully requested.

CONCLUSION

In view of the foregoing, it is respectfully submitted that the pending claims are in condition for allowance. Entry of this amendment and an early notice to this effect is earnestly solicited. Should there be any questions regarding this application, the Examiner is invited to contact the undersigned at the number shown below.

Applicants believe no fee is due with this response. If additional fees are due, please charge our Deposit Account No. 50-2228, under Order Number 022290.0116C1US.

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Exhibit A

E number

From Wikipedia, the free encyclopedia

E numbers are number codes for food additives that have been assessed for use within the European Union (the "E" prefix stands for "Europe").^[1] They are commonly found on food labels throughout the European Union.^[2] Safety assessment and approval are the responsibility of the European Food Safety Authority.^[3] The numbering scheme follows that of the International Numbering System (INS) as determined by the Codex Alimentarius committee^[4] though only a subset of the INS additives are approved for use in the European Union. E numbers are also encountered on food labelling in other jurisdictions, including the GCC, Australia, New Zealand and Israel. The "E" prefix is omitted in Australia and New Zealand. They are increasingly, though still rarely, found on North American packaging, especially in Canada on imported European products.

In casual language in the UK and Ireland, "E number" is used as a pejorative term for artificial food additives, and products may promote themselves as "free of E numbers" even though most of the natural ingredients contain components that also have an E number such as vitamin C (E300) or lycopene (E160d). Thus because, for example, vitamin C has an E number (actually several E numbers, 300-305, for different chemical forms of the vitamin), it is impossible to live off a diet without any substances that have E numbers. "Free of E numbers" then simply means that pure forms of the substances are not intentionally added, even though identical substances certainly exist naturally in many foods.

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 - 2.4 E400–E499 (thickeners, stabilizers, emulsifiers)
 - 2.5 E500–E599 (acidity regulators, anti-caking agents)
 - 2.6 E600–E699 (flavour enhancers)
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Classification by numeric range

100–199 Colours	100–109	yellows (see the full list)
	110–119	orange
	120–129	reds
	130–139	blues & violets
	140–149	greens
	150–159	browns & blacks
	160–199	gold and others
	200–209	sorbates

200–299 Preservatives	210–219	benzoates
	220–229	sulphites
	230–239	phenols & formates (methanoates)
	240–259	nitrates
	260–269	acetates (ethanoates)
	270–279	lactates
	280–289	propionates (propanoates)
	290–299	others
300–399 Antioxidants & acidity regulators	300–305	ascorbates (vitamin C)
	306–309	Tocopherol (vitamin E)
	310–319	gallates & erythorbates
	320–329	lactates
	330–339	citrates & tartrates
	340–349	phosphates
	350–359	malates & adipates
	360–369	succinates & fumarates
400–499 Thickeners, stabilisers & emulsifiers	370–399	others
	400–409	alginates
	410–419	natural gums
	420–429	other natural agents
	430–439	polyoxyethene compounds
	440–449	natural emulsifiers
	450–459	phosphates
	460–469	cellulose compounds
500–599 pH regulators & anti-caking agents	470–489	fatty acids & compounds
	490–499	others
	500–509	mineral acids & bases
	510–519	chlorides & sulphates
	520–529	sulphates & hydroxides
	530–549	alkali metal compounds
	550–559	silicates
	570–579	stearates & gluconates
600–699 Flavour enhancers	580–599	others
	620–629	glutamates
	630–639	inosinates
700–799 Antibiotics	640–649	others
	710–713	
	900–909	waxes
	910–919	synthetic glazes



900–999 Miscellaneous	920–929	improving agents
	930–949	packaging gases
	950–969	sweeteners
	990–999	foaming agents
1100–1599 Additional chemicals	New chemicals that do not fall into standard classification schemes	

NB: Not all examples of a class fall into the given numeric range. Moreover, many chemicals, particularly in the E400–499 range, have a variety of purposes.

Full list

Each additional has its status:

- permitted additional are labeled with *N/A*;
- *forbidden additional* were proven to cause diseases beyond any doubt;
- *unpermitted additional* are those for which conclusive test data is not yet available either due to ongoing tests or no testing;
- *dangerous additional* may be dangerous for people with chronic diseases.

E100–E199 (colours)

Code	Name	Purpose	Status
E100	Curcumin, turmeric	food colouring (yellow-orange)	N/A
E101	Riboflavin (Vitamin B ₂), formerly called lactoflavin (Vitamin G)	food colouring (yellow-orange)	N/A
E101a	Riboflavin-5'-Phosphate	food colouring (yellow-orange)	N/A
E102	Tartrazine (FD&C Yellow 5)	food colouring (lemon yellow)	<i>Unpermitted</i>
E103	Chrysoine resorcinol	food colouring (golden)	<i>Forbidden</i>
E104	Quinoline Yellow WS	food colouring (dull or greenish yellow)	Undergoing a voluntary phase-out in the UK.
E105	Fast Yellow AB	food colouring (yellow)	N/A
E106	Riboflavin-5-Sodium Phosphate	food colouring (yellow)	N/A
E107	Yellow 2G	food colouring (yellow)	N/A
E110	Sunset Yellow FCF (Orange Yellow S, FD&C Yellow 6)	food colouring (yellow-orange)	Banned in Finland, Norway & the UK (voluntarily). Products in the EU require warnings and is evaluating a phase-out.
E111	Orange GGN	food colouring	N/A

E715	Avoparcin ^[citation needed]		
E716	Salinomycin ^[citation needed]		
E717	Avilamycin ^[citation needed]		

E900–E999 (miscellaneous)

Code	Name	Purpose	Status
E900	Dimethyl polysiloxane (anti-foaming agent)	anti-caking agent	N/A
E901	Beeswax , white and yellow	glazing agent	N/A
E902	Candelilla wax	glazing agent	N/A
E903	Carnauba wax	glazing agent	N/A
E904	Shellac	glazing agent	N/A
E905	Paraffins		N/A
E905a	Mineral oil	anti-foaming agent	N/A
E905b	Petrolatum		N/A
E905c	Petroleum wax (i)Microcrystalline wax (ii) Paraffin wax	glazing agent	N/A
E906	Gum benzoic	flavour enhancer	N/A
E907	Crystalline wax	glazing agent	N/A
E908	Rice bran wax	glazing agent	N/A
E909	Spermaceti wax	glazing agent	N/A
E910	Wax esters	glazing agent	N/A
E911	Methyl esters of fatty acids	glazing agent	N/A
E912	Montan wax	glazing agent	<i>Unpermitted</i>
E913	Lanolin, sheep wool grease	glazing agent	N/A
E914	Oxidized polyethylene wax	glazing agent	<i>Unpermitted</i>
E915	Esters of colophony	glazing agent	N/A
E916	Calcium iodate		<i>Unpermitted</i>
E917	Potassium iodate		<i>Unpermitted</i>
E918	Nitrogen oxides		<i>Unpermitted</i>
E919	Nitrosyl chloride		<i>Unpermitted</i>
E920	L-cysteine	improving agent	N/A
E921	L-cystine	improving agent	N/A
E922	Potassium persulfate	improving agent	<i>Unpermitted</i>
E923	Ammonium persulfate	improving agent	<i>Unpermitted</i>
E924	Potassium bromate	improving agent	N/A
E924b	Calcium bromate	improving agent	<i>Unpermitted</i>
E925	Chlorine	preservative, bleach, improving agent	<i>Unpermitted</i>

E1440	Hydroxy propyl starch (emulsifier)	thickening agent	N/A
E1441	Hydroxy propyl distarch glycerine (stabiliser)	thickening agent	N/A
E1442	Hydroxy propyl distarch phosphate (stabiliser)	thickening agent	N/A
E1443	Hydroxy propyl distarch glycerol		N/A
E1450	Starch sodium octenyl succinate (emulsifier) (stabiliser)	thickening agent	N/A
E1451	Acetylated oxidised starch (emulsifier)	thickening agent	N/A
E1501	Benzylated hydrocarbons		N/A
E1502	Butane-1, 3-diol		N/A
E1503	Castor oil	resolving agent	N/A
E1504	Ethyl acetate	flavour solvent	N/A
E1505	Triethyl citrate	foam stabiliser	N/A
E1510	Ethanol		N/A
E1516	Glyceryl monoacetate	flavour solvent	N/A
E1517	Glyceryl diacetate or diacetin	flavour solvent	N/A
E1518	Glyceryl triacetate or triacetin	humectant	N/A
E1519	Benzyl alcohol		N/A
E1520	Propylene glycol	humectant	N/A
E1521	Polyethylene glycol 8000 ^[5]		N/A
E1525	Hydroxyethyl cellulose	thickening agent	N/A

Notes

- [^] UK Food Standards Agency
- [^] European Directive 95/2/EC on food additives other than colours and sweeteners
- [^] Food Additives and Ingredients Association, no date, *Frequently Asked Questions*, accessed 6 March 2010
- [^] Codex Alimentarius. "Noms de Categorie et Systeme International de Numerotation des Additifs Alimentaires". http://www.codexalimentarius.net/download/standards/7/cxg_036f.pdf. Retrieved 2 April 2009.
- [^] New Zealand Food Safety Authority. "Identifying Food Additives". <http://www.nzfsa.govt.nz/consumers/chemicals-nutrients-additives-and-toxins/food-additives.pdf>. Retrieved 16 January 2010.

See also

- Hydrolyzed protein
- List of food additives
- List of food additives, Codex Alimentarius

External links

- Codex Alimentarius
- E-codes and ingredients search engine with details/suggestions for Muslims
- Current EU approved additives and their E Numbers
- Food Additives in the European Union

- Halal Status for E-Numbers

Retrieved from "http://en.wikipedia.org/wiki/E_number"

Categories: [Food additives](#) | [Chemical numbering schemes](#) | [Chemistry lists](#)

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